IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and NOVOPHARM, LTD., Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	PUBLIC VERSION C.A. No. 02-1512 (SLR) CONSOLIDATED
IMPAX LABORATORIES, INC., Counterclaim Plaintiff, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 03-120 (SLR) CONSOLIDATED
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-340 (SLR) CONSOLIDATED
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-360 (SLR) CONSOLIDATED

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT DISMISSING PLAINTIFFS' SHAM LITIGATION AND *WALKER PROCESS* CLAIMS RELATING TO THE TABLET CASES

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INTRODUCTION

Defendants respectfully submit this Reply Brief in further support of their motion for summary judgment dismissing Plaintiffs' sham litigation and *Walker Process* claims relating to the Tablet Cases. Defendants are filing a separate Reply relating to the Capsule Cases.

In responding to this motion, Plaintiffs were required to come forward with evidence sufficient to establish, clearly and convincingly, that Defendants' positions in the underlying patent cases were "objectively baseless" and did not present fair grounds for litigation under *Professional Real Estate Inventors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 51 (1993) ("*PRE*").[1] Plaintiffs have not come close to meeting their burden. Plaintiffs' arguments and evidence regarding the underlying infringement claims show that there were fair grounds for litigation.[2] The same holds true for the allegations of inequitable conduct and *Walker Process*, based on the failure of a declarant to recall a memo addressed to him and others sent six years earlier. That is not enough to avoid summary judgment. Drawing all reasonable inferences in Plaintiffs' favor, they have not come forward with evidence – let alone clear and convincing evidence – sufficient to meet their burden of proving that Defendants' positions were objectively baseless, as required under the objective prong of the *PRE* test.

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1 *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254-55 (1986); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003); *Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH*, 524 F.3d 1254 (Fed. Cir. 2008) ("[T]o survive summary judgment, the party challenging . . . statements [regarding infringement] must present affirmative evidence sufficient for a reasonable jury to conclude that the patentee acted in bad faith, in light of the burden of clear and convincing evidence that will adhere at trial.").

2 The arguments Plaintiffs do *not* raise are just as noteworthy as their actual arguments. *Plaintiffs* do not say *anything* about validity, thereby conceding the objective reasonableness of Defendants' positions on validity. On infringement, Teva and Impax each address only two limitations of the asserted claims, thereby conceding that there were objectively reasonable grounds for asserting infringement for all other limitations. Therefore, partial summary judgment dismissing Plaintiffs' claims of "sham litigation" based on validity and infringement for all other claim terms is required.

Teva and Impax both flavor their Answering Briefs with innuendos about Defendants' intent that has no relevance to the "objective" prong of *PRE*.

ARGUMENT

I. CASE LAW DEFEATS IMPAX'S ARGUMENTS ON THE ALLEGED INADEQUACY OF DEFENDANTS' PRE-SUIT INVESTIGATION

Impax (but not Teva) relies on assertions addressed to the adequacy of Defendants' pre-suit investigation. Indeed, Impax begins its argument by asserting that the supposed "absence of an adequate pre-filing investigation" is evidence that the underlying litigation was "objectively baseless" and that Defendants' allegations were "objectively unreasonable." Impax Br. at 21 (D.I. 531 in C.A. 03-120-SLR); *see also id.* at 25.

A recent Federal Circuit decision defeats Impax's argument. In *Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH*, 524 F.3d 1254 (Fed. Cir. 2008), as here, an antitrust plaintiff tried to satisfy the "objective prong" of the *PRE* test by challenging the adequacy of the defendant's pre-suit investigation. The Federal Circuit unequivocally rejected that theory as having "nothing to do" with the relevant issues:

> **Dominant's focus on the contention that there was no indication that Schachtner [the patentee's counsel] had performed a sufficient analysis,** though arguably relevant on the issue of substantive intent, **had nothing to do with the issue of whether Schachtner's contentions were *objectively* baseless.** (Italics in original; bold type added).

Dominant, 524 F.3d at 1264. The court emphasized that objective baselessness under *PRE* focuses on the record ultimately developed; the adequacy of a pre-suit invention has no bearing on the issue:

> In other words, **objective baseless requires a determination based on the record ultimately made in the infringement proceedings** ..., and **not on the basis of the information available to the patentee at the time the allegations were made.**

Id.

Impax tries to distinguish *Dominant* as a case where the patentee ultimately prevailed in the underlying infringement action. But the broad rule set forth in *Dominant* is not confined to such cases. Under *Dominant*, Impax's arguments concerning the adequacy of Defendants' pre-suit investigation have absolutely "nothing to do" with the "objective reasonableness" prong of *PRE*.

In 2006, when Judge Jordan denied Defendants' motion to dismiss, *Dominant* had not yet been decided. As Impax (correctly) notes, Judge Jordan treated the alleged absence of an adequate pre-suit investigation as "relevant in denying Abbott and Fournier's motion to dismiss." Impax Br. at 21 (D.I. 531 in C.A. 03-120-SLR), *citing Abbott Labs v. Teva Pharms.*, 432 F. Supp. 2d 408, 425 (D. Del. 2006). *Dominant* now establishes that such evidence "has nothing to do" with the objective prong of the *PRE* test. To the extent Judge Jordan relied on the alleged absence of a pre-suit investigation, his decision is not a correct application of the law as it now stands.

II. THE DENIAL OF TEVA'S AND IMPAX'S MOTIONS FOR SUMMARY JUDGMENT IN THE UNDERLYING CASES IS EVIDENCE THAT THERE WERE DISPUTED ISSUES THAT PRESENTED OBJECTIVELY REASONABLE GROUNDS FOR LITIGATION

Some issues where Plaintiffs accuse Defendants of engaging in sham litigation were previously before this Court in the Tablet Cases, and this Court found sufficient merit in Defendants' positions to warrant the denial of Teva's and Impax's motions for summary judgment. As Defendants demonstrated (Opening Brief at 17-20 (D.I. 510 in C.A. 03-120-

SLR)), the denial of Plaintiffs' summary judgment motions in the Tablet Cases, in and of itself, is evidence that there were objectively reasonable grounds for litigation under *PRE*.

In response, Plaintiffs cite two district court decisions for the proposition that denial of summary judgment in the underlying case "does not preclude" a finding of objective baselessness. *See* Impax's Br. at 31 (D.I. 531 in C.A. 03-120-SLR).[3] The weight of authority supports a different conclusion.[4]

At a minimum, the denial of Plaintiffs' summary judgment motions is evidence that Defendants' positions were not objectively baseless. The recent decision in *Dominant* is again instructive. In *Dominant*, the Federal Circuit relied on "the ITC's denial of [the antitrust plaintiff's] motion for summary judgment" in the underlying case, and on the ALJ's determination "that a trial was necessary," as evidence that the defendant's infringement allegations were not "objectively baseless." 524 F.3d at 1263-64. This factor is equally applicable here.

III. THE ASSERTIONS OF INFRINGEMENT IN THE TABLET CASES WERE OBJECTIVELY REASONABLE

Prior to this motion, Plaintiffs were accusing Defendants of engaging in sham litigation with respect to a host of infringement issues. Except for three limitations, Plaintiffs

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[3] *In re Wellbutrin SR Antitrust Litig.*, 2006 WL 616292 (E.D. Pa. 2006); *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 362-65 (D. Mass. 2004).

[4] *See Twin City Bakery Workers & Welfare Fund v. Astra Akltiebalag*, 207 F. Supp. 2d 221 (S.D.N.Y. 2002); *Gen-Probe, Inc. v. Amoco Corp.*, 926 F. Supp. 948, 958 (S.D. Cal. 1996) ("A denial of summary judgment means that the non-moving party has produced enough evidence that a *rational* jury could find in its favor."); *Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.*, 870 F. Supp. 8, 10-11 (D. Mass. 1994) ("If ... [plaintiff] survives a summary judgment motion ... that [it] is entitled to judgment in its favor on the [sham litigation] counterclaims ...."); *Harris Custom Builders v. Hoffmeyer*, 834 F. Supp. 256, 261-62 (N.D. Ill. 1993); *see also Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) ("We find it difficult to agree that [a] defense was 'baseless' when it survived a motion for summary judgment . . . ").

have now abandoned those arguments. Teva and Impax both challenge the objective reasonableness of Defendants' allegations concerning the "hydrophilic polymer" limitation. In addition, Teva addresses the limitation requiring "20-45% micronized fenofibrate," and Impax addresses equivalence for "hydrosoluble carrier."

A. The "Hydrophilic Polymer" Limitation

The dispute in the Tablet Cases on "hydrophilic polymer" involved issues of claim construction. Defendants relied on the ordinary meaning of "hydrophilic polymer," as "any high molecular weight compound of repeating molecular units having an affinity towards water." Plaintiffs do not dispute that this is the term's ordinary meaning. Although this Court ultimately adopted the construction that Teva and Impax offered, it stated immediately following the *Markman* hearing that Defendants' litigation positions *did not* reflect any bad faith. D.I. 297 in C.A. 02-1512-SLR at 89:14-90:6.

Teva and Impax asserted in the underlying cases that the specification defines "hydrophilic polymer" as a polymer that "dissolve[s] in water and form[s] a gel." But read "as a whole," *Alloc, Inc. v. ITC*, 342 F.3d 1361, 1370 (Fed. Cir. 2003), the specification is not consistent in its use of this claim term. In particular, the passage that Teva and Impax relied upon is inconsistent with a different passage that uses the same term in a broader sense.

Plaintiffs do not deny that the specification uses the term "hydrophilic polymer" in different ways. Although one might resolve this "perceived inconsistency" by adopting Teva's and Impax's proposed construction, Impax Br. at 26 (D.I. 531 in C.A. 03-120-SLR), *quoting* D.I. 245 at 16-17, resolving it by adopting Defendants' construction would have been consistent with the ordinary meaning and with Federal Circuit precedent. *See Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003) ("[V]aried use of a

disputed term [in the specification] attests to breadth of a term, rather than providing a limiting definition.").

Even the passage Plaintiffs relied upon could be reasonably read as supporting Defendants' construction. That passage described a "hydrophilic polymer" as meaning a substance with an affinity to water that can "dissolve therein *and* form a gel." DJA-1508, '405 Patent, at 4:36-49 (italics added).[5] In the Tablet Cases, Defendants showed that a standard dictionary indicates that the term "and" sometimes is used in a disjunctive sense, to connote alternatives. The Federal Circuit recently applied this definition in *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (citing *Webster's Third New International Dictionary* (2002)). Plaintiffs have no answer to this point and simply ignore it.

Although Judge Jordan adopted the construction that Teva and Impax advocated, that does not mean that Defendants' proposed construction was objectively baseless. No doubt virtually every district court judge with a patent litigation docket has had a claim construction ruling reversed by the Federal Circuit, and recognizes that a court's rejection of a claim construction does not mean that the proponent of the construction was engaging in "sham litigation" or taking an objectively baseless position.

Plaintiffs do not deny that under Defendants' claim construction, their accused products would have met the "hydrophilic polymer" limitations in all of the Stamm patents.

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[5] Citations to "DJA" refer to pages of Defendants' Joint Appendix, filed with Defendants Opening Brief (D.I. 510 in C.A. 03-120-SLR).

B. The "20 to 45% Micronized Fenofibrate" Limitations

Teva (but not Impax) challenges Defendants' allegations of infringement of the "20 to 45% micronized fenofibrate" limitations. Defendants' position was objectively reasonable under *PRE*. *See* Defendants' Opening Brief at 24-25 (D.I. 510 in C.A. 03-120-SLR).

Under the undisputed claim construction, "micronized" fenofibrate has a particle size of 20 microns or less. Defendants' expert Dr. Stephen Byrn of Purdue University analyzed Teva's product, based on Teva's own description of the product in its ANDA as containing [redacted] Applying accepted scientific principles involving the distribution of particle size, Dr. Byrn concluded that [redacted] *See* Byrn Report, DJA-659, 663. Taking into account Teva's manufacturing process and acceptable variations in each tablet, he concluded that, [redacted] *See* Byrn Reports, DJA-547-550, 659, 883-885.

Teva now argues that "simple math" shows that its product will have [redacted] But its "simple math" argument is simply incorrect. Its argument incorrectly assumes that *every* fenofibrate particle [redacted] Teva does not provide any basis for that assumption and none exists. A more appropriate conclusion is the one drawn by Dr. Byrn – [redacted] *See* Byrn Report, DJA-

659, 663. [redacted] Under this sensible analysis, Teva's "simple math" argument collapses. Moreover, Teva's argument ignores [redacted] *See* Byrn Reports, DJA-548-550, 659, 883-885. In Defendants' view, Dr. Byrn's conclusion is correct. At worst, reasonable experts could disagree on this issue.

Indeed, before Impax dropped its "sham litigation" argument for this element, its noninfringement theory was based on a premise that fenofibrate particles would not agglomerate. *See* Byrn Report, DJA-886-887; Levy Report, DJA-Reply 112-115.[6,7] If Defendants' were engaging in "sham litigation" on this issue, as Teva contends, then so was Impax. In reality, the parties' disagreements on this issue and other issues were objectively reasonable – not sham litigation.

When Teva moved for summary judgment in the Tablet Case, it chose not to address this limitation in its opening brief because it had no good arguments to offer. Teva belatedly tried to raise the issue in its summary judgment reply brief. Summary judgment was denied, leaving the issue for resolution at trial. Defendants' position was not objectively baseless under *PRE*. *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1305 (Fed. Cir. 2004)

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6 Citations to "DJA-Reply" refer to pages of Defendants' Joint Appendix – Reply, filed *concurrently* with this brief.

7 [redacted]

(affirming summary judgment of no "sham litigation" and noting that a "reasonable litigant" could rely on the accused infringer's documents describing its accused product).

C. The "Hydrosoluble Carrier" Limitations

Impax challenges the objective reasonableness of Defendants' assertion that the [redacted] in Impax's products infringed the '405 patent's "hydrosoluble carrier" limitation under the doctrine of equivalents (DOE).

In the Tablet Cases, Defendants presented expert testimony, supported by literature in the field, [redacted] Byrn Report, DJA-491-493, 508-523. Defendants' experts showed that [redacted] *See* Def. Opening Br. at 28-29 (D.I. 510 in C.A. 03-120-SLR) (citing testimony from Defendants' experts Drs. McGinity and Byrn). Although Teva's and Impax's experts draw a different conclusion, Defendants' position on infringement under the DOE had an objectively reasonable basis. *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1019-20 (Fed. Cir. 2006) (rejecting a vitiation argument where expert testimony showed insubstantial differences between the limitation and the accused product).

In the Tablet Cases, Impax moved for summary judgment of noninfringement for this limitation based on prosecution history estoppel. The district court denied that motion. Apart from the prosecution history theory that Judge Jordan rejected, Impax did not seek summary judgment on the DOE and would not have had any basis for doing so because there were fair grounds for litigation on that issue.

IV. TEVA AND IMPAX DO NOT DISPUTE THAT THERE WAS AN OBJECTIVELY REASONABLE BASIS FOR DISPUTING THEIR INVALIDITY CONTENTIONS IN THE TABLET CASES

In their Opening Brief at 34-37 (D.I. 510 in C.A. 03-120-SLR), Defendants demonstrated that their positions on validity had an objectively reasonable basis. Teva and Impax do not dispute this, thereby conceding the objective reasonableness of Defendants' positions on validity.

V. THERE WERE OBJECTIVELY REASONABLE BASES FOR DISPUTING TEVA'S AND IMPAX'S ALLEGATIONS OF INEQUITABLE CONDUCT

Plaintiffs argue that the Stamm patents were procured by inequitable conduct. To avoid summary judgment, Plaintiffs were required to come forward with clear and convincing evidence sufficient to establish that there was no objectively reasonable basis for Defendants to oppose their allegations of inequitable conduct. *See Anderson,* 477 U.S. at 254-55. Once again, Plaintiffs cannot meet their burden.

A. Record Evidence Shows that Mr. Reginault Did Not Withhold Information from the PTO in 2003

Plaintiffs' inequitable conduct theory focused on a former Fournier employee, Philippe Reginault. Plaintiffs accused Mr. Reginault of failing to disclose to the PTO certain dissolution data from a memorandum that he may have received in 1997 and from an undated memo that does not list him as a recipient.

Mr. Reginault stated in a sworn declaration (the "2005 declaration") that [redacted]

[redacted]

Mr. Reginault stated that [redacted]

[redacted] *See* Defendants' Opening Brief at 30-34 (D.I. 510 in C.A. 03-120-SLR). Plaintiffs offer no evidence to the contrary.

Plaintiffs deposed Mr. Reginault in the Tablet Cases and again in these actions. They received Mr. Reginault's 2005 declaration before the second deposition, but avoided asking him about its contents. As a result, the statements in the 2005 declaration stand unrebutted and is the information a "reasonable litigant" would consider.

B. There is No Evidence that Mr. Reginault Was Substantively Involved in Prosecution of the Stamm Patents Before 2003

Plaintiffs do not set forth an iota of evidence that Mr. Reginault was aware of the supposedly withheld data when he prepared the 2003 declaration. In the absence of such evidence, Plaintiffs suggest that Mr. Reginault was involved with the Stamm patents earlier, beginning in 1996. However, they cannot point to any facts that support their theory. At a minimum, there were objectively reasonable grounds under *PRE* for opposing Plaintiffs' assertions on this issue.

1. Applicable Law

By statute, the duty of candor to the PTO applies only to inventors, their prosecuting attorneys and patent agents, and other persons who are "substantively involved in the preparation or prosecution of the application." 37 C.F.R. 1.56(c)(3). The duty does not extend to other employees or officers of a patent owner who do not have substantive involvement in preparing or prosecuting a patent.

In deciding whether someone's involvement rises to the level that triggers a duty of candor to the PTO, the law requires substantive involvement with the actual filing or prosecution of a patent. *See Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc.*, 456 F. Supp. 2d 644, 673 (D.N.J. 2006), *aff'd*, 223 Fed. Appx. 999 (Fed. Cir. 2007). Minor involvement with

patent filing or patent prosecution will not suffice. *Id.* Nor will business-related activities that do not involve communications with the PTO. *See Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 92 F. Supp. 2d 857, 872 n.16 (E.D. Wis. 2000) (corporate executives do not owe a duty of candor if they were not substantively involved in the preparation or prosecution of the application and did not disseminate the information in question to the applicants or their attorneys), *aff'd in relevant part*, 31 Fed. Appx. 727, 732 (Fed. Cir. 2002).

The *Janssen* case is particularly instructive. The *Janssen* court held that that Janssen's CEO, who was not an inventor of the patent at issue, did not owe a duty of candor even though he had conducted research in the relevant technology and had asked Janssen's patent attorneys to prepare patent applications when the research had reached the appropriate point. 456 F. Supp. 2d at 675-76. Like Mr. Reginault, Janssen's CEO had never reviewed the patent application or the prosecution history. *Id.*

2. Mr. Reginault Was Not Substantively Involved in Prosecution of the Stamm Patents Before 2003

Mr. Reginault is not an inventor of the Stamm patents. He was not a prosecuting attorney or patent agent for the inventors. He was not substantively involved in preparing or prosecuting the applications for the '670, '405 and '552 Stamm patents. Apart from the 2003 declaration, he did not engage in *any* communications with the PTO. Nor did he advise counsel on what they should communicate to the PTO. His first and only involvement was in 2003, when he was asked to prepare a declaration for use in prosecution of the '881 patent. *See* DJA-47-52; *see also* Reginault Depo., DJA-Reply 14, at 44:11-45:3, 49:16-19.

Plaintiffs offer conclusory mischaracterizations of Mr. Reginault's involvement. But when one focuses on the evidence, it is clear that Mr. Reginault was not substantially involved in prosecution of the Stamm patents prior to 2003.

Mr. Reginault was the director of pharmaceutical development at Fournier in 1996. In that role, [redacted] *See* DJA-47-52; *see also* Reginault Depo., DJA-Reply 8, at 23:13-24:22. Mr. Reginault had prior experience with fenofibrate. He was a named inventor on U.S. Patent No. 4,896,726 (Curtet), which disclosed and claimed a capsule formulation with co-micronized fenofibrate. The '726 patent issued in 1990, and is prior art to the Stamm patents. (The '726 patent was the subject of the Capsule Cases.).

[redacted]

Mr. Reginault [redacted]. For example, there were milestones based on industrial scale-up activities, regulatory activities and the filing of patent applications. *See* TIJA-2169-72;[8] Reginault Depo., DJA-Reply 21, at 111:15-113:7. "Milestone" payments are common in such agreements. Suggesting "milestone" payments is not indicative of substantive involvement in patent prosecution.

[8] TIJA *refers* to Teva Impax Joint Appendix filed concurrently with their Answering Briefs.

In late 1996, Fournier and PharmaPass entered into an agreement for Fournier to acquire PharmaPass's fenofibrate technology. Mr. Reginault subsequently [redacted]

Teva relies on the fact that [redacted] "involve[ment] with the PharmaPass patents, even before the original French application was filed." Teva Br. at 5 (D.I. 622 in C.A. 02-1512-SLR). However, Teva does not, and cannot, assert that Mr. Reginault prepared the graph or suggested its inclusion in the patent application. There is no evidence that Mr. Reginault discussed that issue with anyone. Teva does not, and cannot, explain how receipt of a graph that the inventors later included in their patent is evidence of "involve[ment]" in patent prosecution.

In fact, Mr. Reginault was not involved with the prosecution of PharmaPass's French application. [redacted]. *See* Reginault Depo., DJA-Reply 12, at 38:7-19; DJA-47-52. [redacted] *See* Reginault Depo., DJA-Reply 12, 14, at 39:21-41:19; 48:21-49:19; DJA-47-52. [redacted]

Teva also offers a conclusory assertion that Mr. Reginault "routinely provided technical assistance to Fournier's patent division and did so in connection with patents regarding fenofibrate." Teva Br. at 4-5 (D.I. 622 in C.A. 02-1512-SLR). Teva's statement is potentially misleading. Teva is primarily referring to communications concerning the Curtet '726 patent, for which Mr. Reginault was a co-inventor, *see* Reginault Depo., DJA-Reply 11-12, 23, at 35:24-38:2, 130:25-131:10. [redacted] *See* Reginault Depo., DJA-Reply 11 at 37:5-10. A single, non-technical conversation regarding a product does not show substantive involvement in patent prosecution. *See Janssen*, 456 F. Supp. 2d at 673 (D.N.J. 2006); 37 C.F.R. 1.56(c)(3).

Plaintiffs also assert that Mr. Reginault participated in a presentation to Abbott in 1997 and was involved in a 2001 audit concerning unspecified fenofibrate patents. Teva Br. at 10-11 (D.I. 622 in C.A. 02-1512-SLR). These events did not involve communications with the PTO, and did not relate to drafting or prosecution of the Stamm patents.

3. The Facts Do Not Support Plaintiffs' Assertion that Two of Mr. Reginault's Ideas Were "Incorporated" into the Patent

Plaintiffs' mischaracterization of Mr. Reginault's role reaches a crescendo with an unsubstantiated and incorrect assertion that "two ideas of Reginault, the use of co-micronized fenofibrate and dissolution in 0.025 M SLS, were incorporated into the U.S. patent application." Teva Br. at 9 (D.I. 622 in C.A. 02-1512-SLR). This contention is not supported by any facts. After extensive document production and depositions, there is not a shred of evidence that inclusion of these matters in the patent application was Mr. Reginault's idea.

As to the patents' reference to 0.025 M SLS, the only facts that Plaintiffs rely upon involve Fournier's use of 0.025 M SLS in its internal testing. *See* Teva Br. at 6-11 (D.I. 622 in C.A. 02-1512-SLR). However, Plaintiffs neglect to mention that [redacted] *See* D.I. No. 303 in C.A. 02-1512-SLR [redacted] Plaintiffs do not cite any evidence to support their theory that Mr. Reginault suggested that a reference to 0.025 M SLS be included in the Stamm patents – and no such evidence exists.

Plaintiffs' argument concerning the patent's reference to co-micronized fenofibrate is equally baseless. Plaintiffs suggest that this feature was missing in the French priority application and was added for the first time in the U.S. application; they then speculate that the idea to include it in the application must have come from Mr. Reginault. Teva Br. at 9-10 (D.I. 622 in C.A. 02-1512-SLR). In fact, the original French application disclosed the use of a co-micronized active ingredient, expressly stating that "[w]hen a surfactant is present, the active ingredient can be co-micronized with the surfactant." *See* TIJA-2240 at ln. 27-28. In addition, claim 4 of the French application claims a composition where the "active ingredient and the surfactant are co-micronized." *Id.* at 2250. The use of co-micronized fenofibrate was in the public record from at least 1990 (long before Fournier's first dealing with PharmaPass), when it was disclosed in the prior art Curtet '726 patent. There is no evidence that Mr. Reginault suggested adding a reference to co-micronized fenofibrate in the application for the Stamm patents.

C. Defendants Had an Objectively Reasonable Basis Under *PRE* for Opposing the Allegations of Inequitable Conduct

According to Plaintiffs, Defendants' assertion that Mr. Reginault was not substantively involved in prosecution prior to 2003 "**is not the *only* reasonable conclusion from these facts.**" Teva Br. at 26 (D.I. 622 in C.A. 02-1512-SLR) (emphasis added). But in order to have objectively reasonable grounds for litigation under *PRE*, Defendants only needed to be advocating a reasonable conclusion based on the evidence – not "the ***only*** reasonable conclusion." *Id.* Objective reasonableness "requires no more than a *reasonable belief* that an allegation may be deemed valid." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 326 (D. Del. 2004), *aff'd* 488 F.3d 982, 1000-1001 (Fed. Cir. 2007). Moreover, Plaintiffs do not cite any facts that warrant a different conclusion.

Viewing the facts in light most favorable to Plaintiffs, there is not a shred of evidence that Mr. Reginault was substantively involved in the prosecution of the Stamm patents prior to his work on the 2003 declaration for the '881 prosecution. Moreover, there is not a shred of evidence that he recalled the allegedly withheld data when he prepared his 2003 declaration.

In the absence of any evidence of Mr. Reginault's substantive involvement, Plaintiffs cannot show that they have clear and convincing evidence that it was objectively baseless to oppose their allegations of inequitable conduct. Summary judgment is accordingly appropriate.

VI. PLAINTIFFS HAVE NOT OFFERED CLEAR AND CONVINCING EVIDENCE OF A *WALKER PROCESS* VIOLATION

Plaintiffs' *Walker Process* claims relate only to the '881 patent. Even as to that patent, Plaintiffs lack the clear and convincing evidence that is needed to support a *Walker Process* claim. To survive summary judgment on their *Walker Process* claim, Plaintiffs were

required to come forward with convincing evidence of "intentional fraud involving affirmative dishonesty, a deliberately planned and carefully executed scheme to defraud … the Patent Office." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998) (quotation omitted); *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007); *Al-Site Corp. v. Opti-Ray Inc.*, 28 U.S.P.Q.2d 1058, 1062-66 (E.D.N.Y. 1993). Plaintiffs have not identified any evidence that meet this high standard, and none exists.

Plaintiffs do not have any evidence – let alone clear and convincing evidence – that Mr. Reginault withheld any information in connection with the '881 prosecution. As discussed above, Mr. Reginault's only involvement with the '881 prosecution was the preparation of his 2003 declaration at the request of patent counsel.[9]

There is no evidence that Mr. Reginault recalled the allegedly withheld data when he prepared his 2003 declaration. And there is no evidence that Mr. Reginault was substantively involved in prosecution of the Stamm patents prior to 2003. In the absence of such evidence, Plaintiffs offer assertions that Mr. Reginault: (a) evaluated PharmaPass's technology in 1996, (b) "focused" on patentability in 1996, (c) approved a dissolution study in 1997, (d) was listed as a recipient of the 1997 memo, (e) had "access" to Fournier's dissolution data[10], and (f) generated a 72-page FDA submission in April 2000 that had one graph that included the dissolution results found in the undated Development Report. Impax Br. at 33-34 (D.I. 531 in C.A. 03-120-SLR).

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9 Fournier's patent counsel confirmed that [redacted] *See* Diebolt Depo., DJA-7.001 at 44:20 to 46:1.

10 [redacted]. Reginault Depo., DJA-Reply 16, at 68:10-19; Blouquin Depo., DJA-Reply 30, at 62:24-63:25. [redacted]. Reginault Depo., DJA-Reply 18-19, at 81:21-82:4.

None of this adds up to clear and convincing evidence that Mr. Reginault knew, recalled, and omitted specific dissolution data in 2003.

Plaintiffs rely on *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341 (Fed. Cir. 2004), *rev'd*, 546 U.S. 394 (2006), but that case is not remotely on point. In *Unitherm*, the evidence showed that the named inventor of the patent had stolen another company's invention outright and then claimed it as his own. These egregious facts have no bearing on any issue here.[11]

Dippin' Dots is more pertinent here. In that case, the Federal Circuit reversed a *Walker Process* fraud finding where the patentee had omitted information about sales of a product in connection with patent prosecution. The court noted that "[w]hile *Walker Process* fraud may be inferred from the facts and circumstances of a case, [a] mere failure to cite a reference to the PTO will not suffice." *Dippin' Dots*, 476 F.3d at 1347 (quotations omitted). Plaintiffs must "prove deceptive intent independently" beyond an omission. *Id.* at 1348. There is simply no "strong evidence that the omission in this case was fraudulent." *Id.*

Walker Process fraud also requires the maintenance of a patent action knowing that the asserted patents were procured by fraud. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998). Plaintiffs fail to address this requirement. They do not dispute the lack of evidence suggesting that Defendants brought and maintained the underlying

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[11] Plaintiffs also cite *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418 (Fed. Cir. 1989), for the proposition that a finding of intent to deceive the PTO is warranted where a wrong-*doer* "simultaneous[ly]" submits data to the FDA "while withholding the same data from the PTO ...." Impax Br. at 34 (D.I. 531 in C.A. 03-120-SLR). The supposedly "simultaneous" events here are the April 2000 submission to the FDA (discussed above) and the June 2003 declaration to the PTO. A gap of three years does not come close to being "simultaneous."

patent action knowing that the asserted patents were procured by fraud. Summary judgment dismissing the *Walker Process* claim is appropriate.

VII. CONCLUSION

For the reasons set forth above and in Defendants' Opening Brief, the Court should grant Defendants' motion for summary judgment dismissing Plaintiffs' sham litigation and *Walker Process* claims.

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Dated: June 16, 2008
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 24, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on June 24, 2008 upon the following parties:

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